

UNITED STATES DISTRICT COURT
DISTRICT OF NEVADA

United States of America,

Plaintiff,

v.

Fresenius Kabi Oncology Limited,

Defendant.

CRIMINAL INFORMATION

2:21-cr-00020-JAD-BNW

VIOLATION:

*Refusal to Permit Access to Records,
21 U.S.C. §§ 331(e), 374(a), 333(a)(1)*

THE UNITED STATES CHARGES THAT:

INTRODUCTION AND GENERAL ALLEGATIONS

At all times relevant to this Information, unless otherwise indicated:

The Federal Food, Drug, and Cosmetic Act

1. The United States Food and Drug Administration (“FDA”) was the agency of the United States responsible for protecting the health and safety of the American public by enforcing the Federal Food, Drug, and Cosmetic Act (“FDCA”), and assuring, among other things, that drugs intended for use in humans were safe and effective for their intended uses. Pursuant to its statutory mandate, the FDA regulated the manufacture, processing, packing, labeling, and shipment in interstate commerce of drugs.

2. The FDCA defined the term “drug” as, among other things, an article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans; an article

1 intended to affect the structure or any function of the body of humans; or an article intended for
2 use as a component of a drug. 21 U.S.C. §§ 321(g)(1)(B), (C), & (D).

3 3. An “active pharmaceutical ingredient” (or “API”) was any substance or mixture of
4 substances intended to be used in the manufacture of a drug product and that, when so used,
5 became an active ingredient in the drug product.

6 4. An “active ingredient” was any component of a finished dosage form drug that was
7 intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation,
8 treatment, or prevention of disease, or to affect the structure or any function of the body of humans.
9 21 C.F.R. § 210.3(b)(7).

10 5. A “drug product” was a finished dosage form drug—for example, a tablet, capsule,
11 or solution—that contained an active ingredient. 21 C.F.R. § 210.3(b)(4).

12 6. Under the FDCA, a drug was deemed adulterated if the methods used in, or the
13 facilities or controls used for, its manufacturing, processing, packing, or holding did not conform
14 to or were not operated or administered in conformity with current good manufacturing practice
15 (“cGMP”) to assure that such drug met the requirements of the FDCA as to safety and had the
16 identity and strength, and met the quality and purity characteristics, which it purported or was
17 represented to possess. 21 U.S.C. § 351(a)(2)(B).

18 7. The term “current good manufacturing practice” included the implementation of
19 oversight and controls over the manufacture of drugs to ensure quality, including managing the
20 risk of and establishing the safety of raw materials, materials used in the manufacturing of drugs,
21 and finished drug products. 21 U.S.C. § 351. Among other things, current good manufacturing
22 practice for API included the following practices:
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1 a. The preparation and retention of a “batch production record” containing complete
2 information relating to the production and control of each batch of API. A “batch” was a specific
3 quantity of an API that was intended to have uniform character and quality, within specified limits,
4 and was produced according to a single manufacturing order during the same cycle of manufacture.
5 21 C.F.R. § 210.3(b)(2).

6 b. The documentation of all tests and their results as part of the batch production
7 record.

8 c. Except in specific circumstances not relevant herein, the blending of batches only
9 when each batch incorporated into a blend had been manufactured using an established process,
10 and had been individually tested and found to meet appropriate specifications prior to blending.

11 8. As part of its mission to enforce the FDCA and protect the public health, the FDA
12 had the authority to enter and inspect at reasonable times all establishments at which prescription
13 drugs or non-prescription drugs intended for human use were manufactured, processed, packed, or
14 held for introduction into interstate commerce or after shipment in interstate commerce. 21 U.S.C.
15 § 374(a)(1). When conducting such an inspection, the FDA had the authority to inspect all things
16 therein (including records, files, papers, processes, controls, and facilities) bearing on whether
17 prescription drugs or non-prescription drugs intended for human use which were adulterated or
18 misbranded, or which could not be lawfully manufactured, introduced into interstate commerce,
19 or sold, or offered for sale by reason of any provision of the FDCA, had been or were being
20 manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on
21 any violation of the FDCA. *Id.*

22 9. Upon conclusion of such an inspection, if violations were observed, the FDA issued
23 a “Form 483,” otherwise known as “Notice of Inspectional Observations,” to set forth the cGMP
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1 deficiencies observed by the FDA investigator during the inspection. If the violations were
2 significant, the FDA could issue a “Warning Letter” to notify the firm of the agency’s observation
3 that certain of its manufactured products appeared to be adulterated, and that, unless sufficient
4 corrective actions were implemented, further regulatory action could be taken without notice. In
5 some instances, if the violations were significant enough, FDA could proceed immediately to
6 regulatory action such as seizure or injunction. 21 U.S.C. §§ 332, 334.

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8 ***The Defendant and Its Business***

9 10. Defendant FRESenius KABI ONCOLOGY LIMITED (“FKOL”) was an Indian
10 corporation with its corporate headquarters in Gurgaon, India. FKOL was one of several
11 subsidiaries of Fresenius Kabi AG, a German corporation with offices in Bad Homburg, Germany.
12 Fresenius Kabi AG, in turn, was owned by Fresenius SE & Co. KGaA, a German corporation and
13 global provider of healthcare products and services.

14 11. FKOL owned and operated a manufacturing plant located in Kalyani, West Bengal,
15 India (the “Kalyani plant” or the “plant”). The Kalyani plant engaged in the manufacture of APIs
16 (the “Kalyani APIs”) intended for incorporation into oncological drug products, including the
17 prescription drug product Irinotecan. Irinotecan was an oncological drug product used to achieve
18 prolongation of life in terminally ill cancer patients afflicted with metastatic colon or rectal cancer.

19 12. FKOL also owned and operated a manufacturing plant located in Baddi, India (the
20 “Baddi plant”). The Baddi plant manufactured prescription drug products, including Irinotecan,
21 and used Kalyani APIs as components in the manufacture of those prescription drug products.

22 13. FKOL distributed Irinotecan and other prescription drug products made with
23 Kalyani APIs to customers in the United States, who in turn sold the drug products to hospitals
24 and oncology clinics across the United States, including to purchasers in the State of Nevada.
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FKOL also distributed Irinotecan API to third party drug manufacturers who, in turn, incorporated it into prescription drug products intended for distribution within the United States.

The 2013 FDA Inspection

14. On or about January 9, 2013, the FDA notified FKOL that it would be conducting an inspection of the Kalyani plant beginning on January 14, 2013. The FDA informed FKOL that the inspection would evaluate the Kalyani plant's compliance with cGMP in the manufacture of APIs.

15. Upon being notified of the planned FDA inspection, FKOL Kalyani plant management directed employees to remove certain records from the Kalyani plant, and delete certain records from computers at the Kalyani plant, which, if not removed and deleted, could result in the FDA identifying cGMP deficiencies in FKOL's manufacture of APIs.

16. At the direction of FKOL Kalyani plant management, employees identified four computers, two High Performance Liquid Chromatograph ("HPLC") machines, and certain hard-copy documents at the Kalyani plant which contained evidence of the plant's practice of unofficially testing and blending Kalyani APIs to conceal impurities in the APIs. An "impurity" was any component present in an API that was not the API or an excipient of the API.

17. The FKOL Kalyani plant's practice of unofficial testing and blending was a clandestine means of identifying impurity levels in APIs and concealing out-of-specification impurity levels so that they did not appear in the official batch production record. Specifically, Kalyani plant employees would perform tests to determine whether certain batches of APIs were out-of-specification due to their impurity levels. If a given batch was identified as out-of-specification, Kalyani plant employees would attempt to bring it within specification by blending the out-of-specification batch with an in-specification batch to achieve an in-specification impurity

1 level. Kalyani plant employees would not document the unofficial tests, the out-of-specification
2 test results, or the blending activity in the batch production record. Rather, Kalyani plant
3 employees would document only the in-specification tests and results in the batch production
4 record, making it appear to any third-party reviewer of the record that unofficial testing and
5 blending had never occurred.

6 18. Prior to the arrival of the FDA investigator on January 14, 2013, FKOL Kalyani
7 plant employees physically removed the four computers, two HPLC machines, and hard-copy
8 documents (the “removed records”) from the premises of the Kalyani plant. The removed records
9 were stored in the residences of certain FKOL employees and at an offsite company location.
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11 19. Prior to the arrival of the FDA investigator on January 14, 2013, FKOL Kalyani
12 plant employees deleted Excel spreadsheet documentation (the “deleted records”), which
13 contained evidence of the Kalyani plant’s practice of unofficial testing and blending of Irinotecan
14 API, from computers at the plant.
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16 20. The FDA investigator arrived at the Kalyani plant on January 14, 2013, and
17 conducted an inspection of the plant from January 14, 2013 to January 18, 2013. During and
18 throughout the inspection, the FDA investigator was unaware of and was not provided with access
19 to the removed records or the deleted records.
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21 **COUNT ONE**

22 *Refusal to Permit Access to Records*

23 21. The allegations contained in paragraphs one through twenty are realleged and
24 incorporated as if fully set forth herein.

25 22. Beginning no later than January 9, 2013, and continuing until on or about January
26 14, 2013, in an offense begun and committed outside the jurisdiction of any particular State and
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district of the United States, and relating to an article regulated by the FDA under the FDCA and intended for import to the United States, including to the State and District of Nevada,

FRESENIUS KABI ONCOLOGY LIMITED,

the defendant, did, during an FDA inspection, refuse to permit access to and copying of records, to wit, four computers, two HPLC machines, certain hard-copy documents, and Excel spreadsheet documentation, as required by Title 21 United States Code, Section 374(a).

All in violation of Title 21, United States Code, Sections 331(e), 374(a), and 333(a)(1).

FORFEITURE ALLEGATION

Refusal to Permit Access to Records

1. The allegations contained in Count One of this Criminal Information are hereby realleged and incorporated as if fully set forth herein by reference for the purpose of alleging forfeiture pursuant to 18 U.S.C. § 981(a)(1)(C) with 28 U.S.C. § 2461(c) and 18 U.S.C. § 982(a)(7).

2. Upon conviction of the offense charged in Count One of this Criminal Information,

FRESENIUS KABI ONCOLOGY LIMITED,

defendant herein, shall forfeit to the United States of America, any property, real or personal, which constitutes or is derived from proceeds traceable to violations of 21 U.S.C. §§ 331(e) and 374(a), a specified unlawful activity as defined in 18 U.S.C. § 1956(c)(7)(F), involving a Federal health care offense as defined in 18 U.S.C. § 24, or a conspiracy to commit such offense:

defendant herein shall forfeit to the United States of America, property, real or personal, that constitutes or is derived, directly or indirectly, from gross proceeds traceable to the commission of 21 U.S.C. §§ 331(e) and 374(a), involving a Federal health care offense as defined in 18 U.S.C. § 24:

1 an in personam criminal forfeiture money judgment including, but not limited to, at least
2 \$20,000,000 (property).

3 3. If any property subject to forfeiture pursuant to 18 U.S.C. § 981(a)(1)(C) with 28
4 U.S.C. § 2461(c) and 18 U.S.C. § 982(a)(7), as a result of any act or omission of the defendant-


- 5 a. cannot be located upon the exercise of due diligence;
6 b. has been transferred or sold to, or deposited with, a third party;
7 c. has been placed beyond the jurisdiction of the court;
8 d. has been substantially diminished in value; or
9 e. has been commingled with other property which cannot be divided without
10 difficulty,

11 it is the intent of the United States of America, pursuant to 21 U.S.C. § 853(p), as incorporated
12 by 18 U.S.C. § 982(b)(1), to seek forfeiture of any other property of the defendant for the
13 property listed above.

14 All pursuant to 18 U.S.C. § 981(a)(1)(C) with 28 U.S.C. § 2461(c), 18 U.S.C. §
15 982(a)(7), 21 U.S.C. §§ 331(e) and 374(a), and 21 U.S.C. § 853(p).


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